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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,206

07/29/2003

Kei Roger Aoki

17328CON4

1996

7590

05/26/2006

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/630,206	AOKI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,9,12,13,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9,12,13,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 4, 5, 9, 12, 13, 31 and 32 are pending.

Applicants' amendment filed June 22, 2005 is acknowledged, and applicants' response has been fully considered. Claims 1, 9, 12, 31 and 32 have been amended, and claims 28-30 have been cancelled. Thus, claims 1, 4, 5, 9, 12, 13, 31 and 32 are examined.

### **Withdrawn Claim Rejections - Obviousness Type Double Patenting**

2. The previous rejection of claims 1, 4, 5 and 9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U. S. Patent 6,113,915, is withdrawn in view of applicants' amendment to the claim, and applicant's response at pages 4-5 in the amendment filed June 22, 2005.
3. The previous rejection of claims 1, 4, 5, 9, 12, 13 and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-34 of co-pending application 10/630,204, is withdrawn in view of applicants' amendment to the claim, and applicants' cancellation of the claim in the amendment filed June 22, 2005, as well as applicant's terminal disclaimer filed June 22, 2005.
4. The previous rejection of claims 1, 4, 5, 9, 12, 13 and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 11/003,677, is withdrawn in view of applicants' amendment to the claim, and applicants' cancellation of the claim in the amendment filed June 22, 2005, as well as applicant's terminal disclaimer filed June 22, 2005.

**Withdrawn Claim Rejections - 35 USC § 112**

5. The previous rejection of claims 1, 4, 5, 9, 12, 13 and 28-32 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicant's response at pages 7-8 in the amendment filed June 22, 2005.

**Withdrawn Claim Rejections - 35 USC § 102**

6. The previous rejection of claims 1, 4, 5, 9, 12, 13 and 28-32 under 35 U.S.C. 102(b) as being anticipated by Aoki *et al.* (WO 95/17904), is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicant's response at pages 9-10 in the amendment filed June 22, 2005.

7. The previous rejection of claims 1, 4, 5, 9, 12, 13 and 28-32 under 35 U.S.C. 102(e) as being anticipated by First (U.S. Patent 6,063,768), is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicant's response at page 10 in the amendment filed June 22, 2005.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4, 5, 9, 12, 13, 31 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by Binder (WO 95/30431).

Binder teaches a method of reducing headache pain such as vascular headache pain (migraine, Table 1(a)) or a headache pain of neuralgia such as trigeminal neuralgia (Table 1(b),

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page 1, lines 21-27) by administering a therapeutically effective amount of a presynaptic neurotoxin such as botulinum toxin A in mammals including humans (page 5, line 25-page 6, line 16; Example I), where the neurotoxin can be administered extramuscularly or intramuscularly (i.e., electromyographical injection; page 10, line 25-page 11, line 5) at a localized site of pain (page 9, lines 15-21; claims 1, 4, 5, 12, 13, 28, 31 and 32) and the effect to produce paralysis at target site muscles for up to 3 to 6 months (page 11, lines 6-13; claim 9).

### *Conclusion*

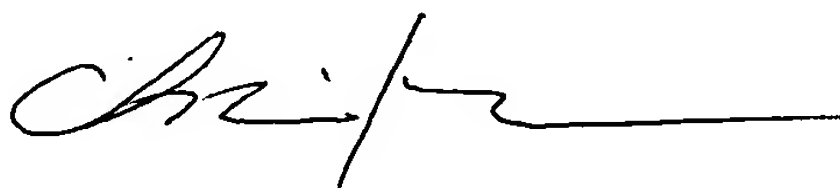
9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

May 16, 2006